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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,408	05/09/2001	Carlos Schuler	015225-005910US	5388

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EXAMINER

PATEL, NIHIR B

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,408

Applicant(s)

SCHULER ET AL.

Examiner

Nihir Patel

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 10,23 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9,11-22,24-32 and 34-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 6, 9

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species figure 3 and sub-species of figures 3a and 3b in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the search for the separate species would not pose an undue burden on the examiner. This is not found persuasive because a search for the separate species and sub-species would pose a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 12-22, and 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritson et al. Patent No. WO 94/16759. Referring to claim 1, Ritson discloses an automatic aerosol medication delivery system and methods that comprises a disposable container 4 (see figure 4) containing a drug formulation; an aerosol generator for aerosolizing the drug formulation; a prevention device 300 (see figures 1-4) which prevents access to the drug formulation when in an inactive state and which permits access to the drug formulation when in an activated state.

Referring to claim 2, Ritson shows that the prevention device comprises an electronic lockout device (see page 23 lines 31-32 and page 24) having a lockout element that is positioned in a dose preventing position when in the inactive state, and is movable to a dosing permitting

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position when electric current is supplied to place the lockout device in the activated state. The batteries (see figure 3) can also be used as an electronic lockout device in Ritson's invention.

Referring to claim 3, Ritson shows that the lockout device further comprises circuitry for supplying electrical current to move the lockout element to the dose permitting position when the lockout device is in the activated state (see page 24).

Referring to claim 4, Ritson shows that the lockout device further comprises a controller having an associated memory for storing a dosing condition, and wherein the controller is configured to send a signal to place the lockout device in the activated state after the dosing condition has been satisfied (see page 38 lines 5-20).

Referring to claim 5, Ritson shows that the container 4 comprises a canister 30, and wherein the aerosol generator comprises a metering valve 32 and an actuator operably coupled to the canister (see figure 3).

Referring to claim 6, Ritson's invention further comprises a housing 40, wherein the canister 30 is reciprocally held within at least a position of the housing between a home position and a dosing position where the actuator is engaged to open the metering valve 32 and to permit the escape of a metered amount of the drug formulation from the canister 30 (see figure 3).

Referring to claim 7, Ritson shows that the lockout element is positioned to prevent engagement of the actuator when in the dose preventing position to thereby prevent opening of the metering valve 32 (see figure 3 and pages 32 and 33).

Referring to claim 8, Ritson shows that the lockout element has a distal end that is engageable with the canister to prevent substantial displacement of the canister into the housing

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40 when the lockout element is in the dose preventing position (see pages 32 and 33 and figure 3).

Referring to claim 9, Ritson shows that upon placement of the preventing device into the activated state, the distal end of the lockout element is retracted to permit displacement of the canister into the housing 40 and to permit engagement of the actuator to open the metering valve (see pages 32 and 33 and figure 3).

Referring to claim 12, Ritson's invention further comprises a dose counter disposed to count the number of doses of the drug formulation dispensed from the container (see figure 3).

Referring to claim 13, Ritson shows that the container 4 is reciprocatably disposed within a housing 40; and wherein the dose counter comprises a dose counting circuit positioned to sense when the container has been reciprocated within the housing (see page 20 and figure 3).

Referring to claim 14, Ritson shows that the dose counter further comprises a display for indicating if the container contains an amount of drug formulation (see figure 3 and page 20).

Referring to claim 15, Ritson's invention further comprises a nozzle operable coupled to the canister 30, and wherein the housing further includes a mouthpiece 20 disposed to receive the drug formulation from the nozzle (see figure 3).

Referring to claim 16, Ritson show that the mouthpiece has a first end and a second end, and wherein the nozzle is positioned within an opening adjacent the first end of the mouthpiece to permit the aerosolized drug formulation to be delivered to a patient upon inhalation through the second end of the mouthpiece (see figure 3).

Referring to claim 17, Ritson discloses an automatic aerosol medication delivery system and methods that does provide a container 4 (see figure 4) having an amount of a drug

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formulation; preventing the transfer of the drug formulation from the container 4 with an electronic lockout device when the lockout device is in an inactive state; and supply electrical current to the lockout device to place the lockout device in an active state, thereby permitting the transfer of the drug formulation from the container (see figure 3 and pages 32 and 33).

Referring to claim 18, Ritson shows that the electronic lockout device comprises a lockout element that is positioned in a dose preventing position when in the inactive state, and further comprising moving the lockout element to a dosing permitting position when electric current is supplied to place the lockout device in the activated state (see figure 3 and pages 32 and 33).

Referring to claim 19, Ritson shows that the container 4 comprises a canister 30 having a metering valve 32 and an actuator, wherein the canister 30 is reciprocatably held within a housing 40 between a home position and a dosing position and further comprising depressing the canister 30 into the housing to the dosing position to engage the actuator and to release a metered amount of the drug formulation when the lockout device is in the active state (see figure 3 and pages 32 and 33).

Referring to claim 20, Ritson's invention further comprises a method for preventing engagement of the actuator when the lockout element is in the dose preventing position (see pages 32 and 33).

Referring to claim 21, Ritson's invention further comprises a method for engaging the canister 30 with the lockout element to prevent movement of the canister to the dispensing position when the lockout element is in the dose preventing position (see pages 32 and 33).

Referring to claim 22, Ritson's invention further comprises a method for disengaging the lockout element from the canister 30 to permit movement of the canister 30 to the dispensing position upon supply of the electrical current (see pages 32 and 33).

Referring to claim 24, Ritson's invention comprises a method for stopping the supply of the electric current to the lockout device after the drug formulation has been transferred from the container 4 (see figure 3 and pages 32 and 33).

Referring to claim 25, Ritson's invention further comprises a method for supplying electric current to the lockout device to permit another dosing only after a certain dosing conditions have been satisfied (see page 20).

Referring to claim 26, Ritson's invention further comprises a method for counting the number doses transferred from the container (see page 20).

Referring to claim 27, Ritson's invention further comprises a method for displaying whether the container 4 contains an amount of drug formulation based on the number of counts (see page 20).

Referring to claim 28, Ritson discloses an automatic aerosol medication delivery system and methods that comprises a housing 40 (see figure 3) having a mouthpiece 20 (see figure 3); a canister 30 that is movable within the housing 40 when manually depressed into the housing 40, the canister 30 having a metering valve 32 that is operable to release a metered amount of drug formulation from the canister 30; and a control system 200, 300, and 50 to control opening of the valve such that the valve is only opened when a force is manually applied to depress the canister 30 into the housing 40 and when a dosing condition has been satisfied (see figure 3 pages 20, 32, and 33).

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Referring to claim 29, Ritson shows that the control system comprises a controller and a locking mechanism, wherein the controller is configured to send a signal to the locking mechanism to permit opening of the valve once the dosing condition has been satisfied (see pages 32 and 33).

Referring to claim 30, Ritson shows that the dosing condition is the passage of a certain amount of time between dosings, and further comprising an electronic clock coupled to the controller to measure the passage of time between dosings (see page 24 lines 20-25).

Referring to claim 31, Ritson shows that the locking mechanism is normally in a dose preventing position and is movable to a dosing position when electrical current is supplied to the locking mechanism to permit opening of the valve when the canister is depressed (see pages 32 and 33).

Referring to claim 32, Ritson shows that the locking mechanism includes a locking element that engages the canister to prevent depression of the canister into the housing when in the dose preventing position (see pages 32 and 33).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritson et al. Patent No WO 94/16759 in view of Samiotes Patent No. 6,125,844.

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Ritson discloses the applicant's invention as claimed with the exception of stating that the drug formulation is nicotine.

Samiotes discloses a portable oxygen based drug delivery system that does state that the drug formulation could be nicotine (see column 6 lines 20-35). Therefore it would be obvious to modify Ritson's invention by stating that the drug formulation is nicotine so that one knows the limitations of the invention.

Referring to claims 34 and 36, the choice of nicotine as the drug formulation is simply a matter of design choice as stated in Ritson (see page 17 lines 21-24).

Referring to claim 11, the applicant states that a hand-held portable aerosol drug delivery system further comprises a high pressure gas source to assist in aerosolizing the drug formulation when the preventing device is in the activated state whereas in the specifications the applicant clearly states that "optionally, a high pressure gas source maybe provided to assist in aerosolizing the drug formulation when the preventing device is in the activated state". Therefore a high pressure gas source is simply a matter of design choice and depends on where the invention is going to be applied.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP
December 9, 2002


Henry Bennett
Supervisory Patent Examiner
Group 3700